''Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1).''.

SEC. 3. EFFECTIVE DATE.

The amendments made by section 1 shall apply to any application for patent filed on or after the date of enactment of this Act and to any application for patent pending on such date of enactment, including (in either case) an application for the reissuance of a patent.

SECTION-BY SECTION ANALYSIS AND DISCUSSION

SECTION 1. BIOTECHNOLOGICAL PROCESS PATENTS; CONDITIONS FOR PATENTABILITY; NONOBVIOUS SUBJECT MATTER

Section 1 provides a mechanism for applicants to facilitate the procurement of a patent for a biotechnological process that makes or uses a novel and non-obvious biotechnology product, overruling the decision in In re Durden, 763 F.2d 1406 (Fed. Cir. 1985). This section would amend section 103 of title 35, United States Code, to ensure that a biotechnological process would not be considered obvious, and thus unpatentable, if it either makes or uses a composition of matter that itself is novel and non-obvious.

The legislation has an impact on only one element of patentability of biotechnological processes—the element of non-obviousness. There is no guarantee of patentability even if the process claim satisfies the non-obvious provisions of the revised section 103. The process must still satisfy all other requirements of patentability, including novelty and utility among other requirements.

To qualify as non-obvious under this section, the claims to the process and the composition of matter, to which the process is linked, must be contained in either the same application for patent or in separate applications having the same effective filing date. Additionally, the composition of matter and the process at the time it was invented, must be owned by the same person or be subject to an obligation of assignment to the same person.

Section 1 also allows an applicant to demonstrate the independent patentability of a process under current law or proceed under the non-obviousness rule established by this section. Independent patentability may be demonstrated, for example, by showing the non-obviousness of the process through proof that the process demonstrates unpredictable results.

Finally, this section provides five possible definitions of the term ''biotechnological process.'' These definitions limit the applicability of this section to biotechnological process patents. The new definitions are broad enough to include most genetic engineering technologies that are currently being used by biotechnology researchers.

The first proffered definition explains a ''biotechnological process'' as a process of inducing an organism to express a characteristic not naturally associated with it through the methods of genetic engineering or other methods. Such a process may cause an organism to ''express an exogenous nucleotide sequence.'' An example of such a method is the process by which human insulin is produced in commercial quantities. The DNA sequence for human insulin is inserted into the bacteria E. coli so the bacteria begins expressing, or producing, human insulin in its cellular machinery.

This second definition of a ''biotechnological process'' specifies that such a process could be altering an organism to ''inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence.'' A popular example of a product produced by such a process is the Flavr-Savr Tomato. This process involves the alteration of tomatoes to eliminate the inter-cellular production of an enzyme that causes the tomato to rot. By eliminating the expression of this ''rotting'' enzyme, the tomato is allowed to have a longer shelf-life.

The third qualifying definition interprets ''biotechnological process'' as altering an organism to ''express a specific physiological characteristic not naturally associated with said organism.'' The Hepatitis B virus vaccine is produced utilizing such a process. The ''antigen,'' or surface protein to which the human immune system responds, for Hepatitis B is inserted into yeast to yield commercial quantities of the protein. The expression of the protein does not occur naturally in yeast but does so because its genetic coding has been altered. The protein is then removed from the yeast and injected into humans to induce the body to safely and naturally produce an immune reaction to fight the deadly virus, which causes liver damage and cancer. The use of such a process to combat many human and animal diseases, including AIDS.

The fourth qualifying definition comprises ''cell fusion procedures.'' An example of such a process is the method used for producing monoclonal antibodies, referred to by scientists as ''hybridoma technology.'' This technology involves fusing spleen cells that produce certain desired antibodies to a specialized ''immortal'' cell—usually a cancer cell—that no longer produces an antibody of its own. The resulting fused cells, or ''hybridomas,'' grow continuously and rapidly like a cancer cell, yet they produce the desired antibodies. Monoclonal antibodies are widely used in targeting special cells to diagnose infections and cancer. The possibility of their use in the direct treatment of cancer and immune disorders is currently a major focus of biomedical researchers.

Finally, the fifth definition of a qualifying ''biotechnological process'' is described as any method of using a final product that has been produced by a process defined by any of the other four definitions provided or a combination of the processes thereof.

SECTION 2. PRESUMPTION OF VALIDITY

This section provides that if a patent claim to a composition of matter—either the starting material or the final product—is held invalid because the Patent and Trademark Office determines that it is non-obvious, the patent process application that is dependent on that composition of matter will no longer be entitled to rely on that composition of matter for a presumption of non-obviousness. In such a case, the inventor must show that such a process is non-obvious without relying on this legislation.

SECTION 3. EFFECTIVE DATE

The amendments made by this act are effective on the date of enactment. The amendments will apply to all patents filed on or after the date of enactment and all patent applications, including applications for the reissuance of a patent, pending on the date of enactment.

MESSAGES FROM THE HOUSE

At 2:24 p.m., a message from the House of Representatives, delivered by Ms. Goetz, one of its reading clerks, announced that the House has passed the following bill, in which it requests the concurrence of the Senate.

H.R. 2405. An act to authorize appropriations for fiscal years 1996 and 1997 for civilian science activities of the Federal Government, and for other purposes.

At 6:09 p.m., a message from the House of Representatives, delivered by Ms. Goetz, one of its reading clerks, announced that the House has passed the following bills, without amendment.

S. 227. An act to amend title 17, United States Code, to provide an exclusive right to perform sound recordings publicly by means of digital transmissions and for other purposes.

S. 268. An act to authorize the collection of fees for expenses for triploid grass carp certification inspections, and for other purposes.

S. 1111. An act to amend title 35, United States Code, with respect to patents on biotechnological processes.

The message also announced that the Speaker appoints Mr. OBERSTAR as a conferee in the committee of conference on the disagreeing votes of the two Houses on the amendment numbered 4 of the House to the bill (S. 395) to authorize and direct the Secretary of Energy to sell the Alaska Power Administration, and to authorize the export of Alaska North Slope crude oil, and for other purposes; to fill the vacancy resulting from the resignation from the House of Representatives of Mr. Mineta.

The message further announced that the House disagrees to the amendment of the Senate to the bill (H.R. 1655) to authorize appropriations for fiscal year 1996 for intelligence and intelligence-related activities of the U.S. Government, the Community Management Account, and the Central Intelligence Agency Retirement and Disability System, and for other purposes, and agrees to the conference asked by the Senate on the disagreeing votes of the two Houses thereon; and appoints the following Members as the managers of the conference on the part of the House:

From the Permanent Select Committee on Intelligence, for consideration of the House bill, and the Senate amendment, and modifications committed to conference: Mr. COMBEST, Mr. DORNAN, Mr. YOUNG of Florida, Mr. HANSEN, Mr. LEWIS of California, Mr. GOSS, Mr. SHUSTER, Mr. MCCOLLUM, Mr. CASTLE, Mr. DICKS, Mr. RICHARDSON, Mr. DIXON, Mr. TORRICELLI, Mr. COLEMAN, Mr. SKAGGS, and Ms. PELOSI.

From the Committee on National Security for the consideration of defense tactical intelligence and related activities: Mr. SPENCE, Mr. STUMP, and Mr. DELLUMS.

As additional conferees from the Committee on International Relations, for consideration of section 303 of the House bill, and section 303 of the Senate amendment, and modifications committed to conference: Mr. GILMAN, Mr. SMITH of New Jersey, and Mr. BERMAN.

MEASURES REFERRED

The following bill was read the first and second times by unanimous consent and referred as indicated: